

## Protest under 37 CFR 1.29(a)

To: Assistant Commissioner for Patents  
Washington, D.C. 20231

Name of Applicant: Harlan Waksal: represented by Debra A. Sommerville and  
Richard De Lucia, Esq and Kenyon&Kenyon,Jay  
Alexander Lawrence at Morrison and Foerster

Application Number: 20030157104 A1  
Filing date of Application: November 30, 2001  
Publication date of Application: August 31, 2003  
Title of Invention: Treatment of refractory human tumors with  
epidermal growth factor receptor antagonists  
Group Unit: Not Known  
Name of Examiner: Jasmine Chambers, Director  
Current Status and Location of Application: Not Known  
**ATTENTION Office of Technology Center 1600, inventions related to biotechnology  
and biochemistry**

The patent application by Harlan Waksal contains specifications and a claim to an invention that I conceived. Therefore, this application is in violation of 35 USC 102(g). This invention which I conceived and related in confidence to Harlan Waksal, his brother Sam Waksal, presently incarcerated, their counsel Tom Gallagher and their patent counsel Debra Somerville of Kenyon & Kenyon is the making and use of small peptide equivalents of the monoclonal described in this application. I conceived of what is now claimed as claim 4. Claim 4 is dependent claim which claims a method wherein the antagonist is a small molecule that binds specifically with EGFR/HER1. See below:

1. A method of inhibiting the growth of refractory tumors that are stimulated by a ligand of epidermal growth factor receptor (EGFR) in human patients, comprising treating the human patients with an effective amount of an EGFR/HER1 antagonist.
4. A method according to claim 1 wherein the antagonist is a small molecule that binds specifically with EGFR/HER1.

The methods to identify and isolate such a small molecule are now published in my recently issued patent that has been in the patent office for 18 years. My application was known to all in the biotech office during this extended period. See US patent 6, 605, 448

Therefore, since inventorship in the US is to the person who conceived of the invention, either this application corrects the inventorship under various aspects of 1.47 to include me or the application and its parent should be denied.

Find attached a Confidentiality Agreement signed between myself and Imclone where the invention I conceived and is now claim 4 of Harlan Waksal's application was described.

I, hereby affirm that the above statements are true and that Kenyon & Kenyon ie Imclone's lawyers and Harlan Waksals lawyer J.Alexander Lawrence at Morrison &

To: before final TC1600 USPTO  
Sent by the Award Winning Cheyenne Bitware

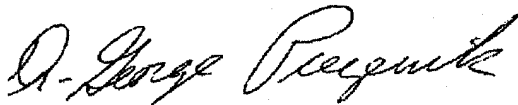
From: George

10/05/03 1:25:06 Page 2 of 4

Foerster have been served with copies of the above by e mail, fax and first class mail this  
Oct. 4, 2003.

I request that you consider this protest.

Sincerely yours,



Prof. George Pieczenik

Appendix 1 Confidentiality Agreement

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### CONFIDENTIALITY AGREEMENT

ImClone Systems Incorporated, having a place of business at 180 Varick Street, 18th Floor, New York, New York 10014 (hereinafter called "ImClone"); and George Plectzenik, having a place of business at 412 East 55<sup>th</sup> Street, New York, New York 10022 (hereinafter called "Individual") expect to discuss the prospect of Individual providing information in connection with functional genomics to ImClone ("Consulting"). For each a discussion to take place, information that may be proprietary may be disclosed to ImClone by Individual or by ImClone to Individual. For the purpose of making ImClone and Individual (hereinafter, collectively, "the Parties") to hold the discussion described above, the Parties agree to disclose and to receive proprietary information from the other on the following terms and conditions:

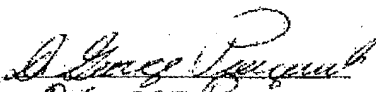
1. For the purpose hereof, the term "Proprietary Information" shall mean all information relating to Consulting that is disclosed to the receiving Party. Proprietary Information includes, but is not limited to, information relating to marketing strategy, science, finance, business, intellectual property, and law. Proprietary Information does not include information that (i) is in the public domain at the time of disclosure; (ii) is in the possession of the receiving Party prior to the time of disclosure; (iii) after disclosure, enters the public domain through no act or omission of the receiving Party; (iv) after disclosure, is received by the receiving Party from a third Party unless the receiving Party knows the third Party is not entitled to receive and transfer the information.
2. The receiving Party shall treat each item of Proprietary Information received from the other Party as confidential for a period of three (3) years from the date of receipt of each item, and shall not use such Proprietary Information for any purpose other than that described above. To treat as confidential shall mean that the receiving Party will not disclose Proprietary Information to any third Party without the prior written consent of the disclosing Party, and will take commercially reasonable precautions, and in any event not less than the same precautions to prevent the unauthorized disclosure of Proprietary Information to third Parties that it takes to prevent the unauthorized disclosure of its own confidential information.

IN WITNESS WHEREOF, the Parties hereto have caused this instrument to be  
executed by their duly authorized officers.

IMCLONE SYSTEMS INCORPORATED

By:   
Print: John B. Landes  
Title: Senior Vice President  
General Counsel  
Date: 2/1/01

GEORGE PIECZENIK

By:   
Print: GEORGE PIECZENIK  
Title: \_\_\_\_\_  
Date: 2/1/01

2

IN WITNESS WHEREOF, the Parties hereto have caused this instrument to be executed by their duly authorized officers.

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GEORGE PIECZENIK

By: [Signature]  
Print: GEORGE PIECZENIK  
Title: \_\_\_\_\_  
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3. The Parties shall use their best efforts to restrict the communication of Proprietary Information to their employees and representatives who need to know to the extent necessary for the purpose hereof.

4. Each authorized employee or representative to whom any Proprietary Information is communicated or given shall be informed that the information is confidential and proprietary and shall agree not to disclose or give the information to others.

5. Each authorized employee or representative to whom any Proprietary Information is communicated or given shall agree not to use any of said information except for the purpose of entering into the discussion contemplated hereunder.

6. Notwithstanding the foregoing, nothing contained in this agreement shall be construed as creating an express or implied license to practice Proprietary Information.

7. This Confidentiality Agreement shall be interpreted in accordance with the laws of the State of New York, without regard to its choice-of-law principles.

8. This Agreement is intended by the Parties hereto as the final expression of their understanding and is the complete and exclusive statement of the terms hereof notwithstanding any oral representations or statements to the contrary heretofore made. This Agreement contains all of the representations and understandings between the Parties hereto. No modifications of this Agreement or waiver of the terms and conditions hereof shall be binding upon either Party unless approved in writing by an authorized representative of both Parties or shall be effected by the acknowledgment of acceptance of any forms containing other or different terms and conditions whether or not signed by an authorized representative of one of the Parties. No modification or release shall be effective unless in writing signed by the Parties.

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10/05/03 1:31:58 Page 4 of 5

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